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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,081	11/13/2003	David H. Coy	00537-164003	7933

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,081

Applicant(s)

COY ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21, 23 and 32-43 is/are rejected.
- 7) ☒ Claim(s) 22 and 24-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's amendment received July 29, 2005.

Claims 1-17 are cancelled. Claims 18-43 are currently pending.

Upon further consideration of the claims, and in view of the fact that each application is examined on its own merits, the following new ground(s) of rejection is respectfully submitted.

Allowability is withdrawn, and prosecution on the merits is reopened.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, substituent "R3" is not specifically defined. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention.

For this office action, however, "R3" will be given the definite described in claim 23.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

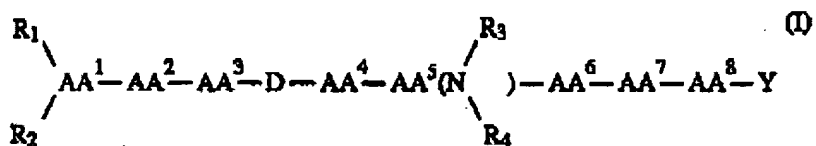
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 19, 20, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Coy et al., 5,462,926 (already of record).

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Coy et al. disclose somatostatin analogs represented by the Formula (I):



wherein

AA¹ is the D- or L-isomer of an aromatic α -amino acid;

AA² is the D- or L-isomer of Cys;

AA³ is F₅Phe, Phe, or X-Phe in which X is halogen, NO₂, CH₃, or OH;

AA⁴ is Trp or an aromatic α -amino acid;

AA⁵ is Lys or Orn;

AA⁶ is Thr or Ser;

AA⁷ is the D- or L-isomer of Cys;

AA⁸ is the D- or L-isomer selected from the group consisting of an aromatic α -amino acid;

wherein R1-R4 are as defined in col. 3, line 61 to col. 14, line 15. Specific species disclosed by

Coy et al. are H_2 -D-Nal-D-Cys-Tyr-D-Trp-Lys-Val-Cys-Nal-NH₂ (Anal. log #10);

and H_2 -D-Nal-D-Cys-Tyr-D-Trp-Lys-Thr-Cys-Nal-NH₂; . Please see col. 4, line 25; col. 3, lines 28-29.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

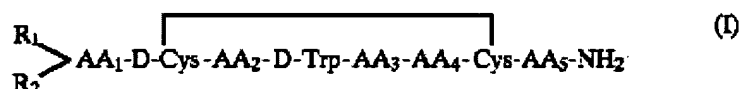
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 18, 19, 20, 23, 32-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Bass et al., 5,846,934 (already of record).

Bass et al. disclose the invention substantially as claimed. Specifically, Bass et al. disclose a somatostatin antagonist having the formula (I):



wherein

R_1 and R_2 are each independently H, C_1 - C_8 alkyl, COR or COOR;

AA_1 is the D or L isomer of an aromatic α -amino acid optionally substituted with one to three NO_2 , CN, Cl, Br, I, F, COR_3 , $COOR_3$ or OR_3 groups;

AA_2 is the D or L isomer of an aromatic α -amino acid optionally substituted with one to three NO_2 , CN, Cl, Br, I, F, COR_4 , $COOR_4$ or OR_4 groups;

AA_3 is the D or L isomer of Arg, Lys, Orn or Cit;

AA_4 is Val, Leu, Ile, Abu, Nle, Thr, 3- R_5 -Ser, Thr(Bzl) or Ser(Bzl), with the proviso that when AA_4 is Thr, then AA_1 must be the L isomer;

AA_5 is the D or L isomer of an aromatic α -amino acid optionally substituted with one to three NO_2 , CN, Cl, Br, I, F, COR_6 , $COOR_6$ or OR_6 groups, $N(CH_3)$ Ala, $N(R_7)$ - α -amino acid, Thr or Ser, with the proviso that the number of D-amino acid residues within the cyclic portion of the peptide is an even number;

R is C_1 - C_8 alkyl, phenyl, phenyl(C_1 - C_4)alkyl; naphthyl, or naphthyl (C_1 - C_4) alkyl;

R_2 , R_3 , R_4 , R_6 and R_7 are each independently H or C_1 - C_8 alkyl; and

R_5 is H, C_1 - C_8 alkyl, or the D or L isomer of an aromatic α -amino acid optionally substituted with one to three NO_2 , CN, Cl, Br, I, F, COR_6 or OR_6 groups; or the pharmaceutically acceptable salts thereof.

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Bass et al. teach that the peptides of formula (I) may be used in methods for increasing insulin release, increasing the release of growth hormone, increasing the release of glucagons and enhancing growth.

Bass et al. additionally disclose that the peptides of formula (I) are selective for SSTR2 and SSTR5 and there are methods disclosed for imaging cells having somatostatin receptors. Please see col. 1, lines 30-42; col. 2, lines 13-65; Example 4.

Claims 34, 35, 40, 41 are anticipated by Bass et al. because Bass et al. disclose administration of identical peptides to a host using applicant's claimed method steps. Therefore, promotion of angiogenesis or wound healing would be inherent.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

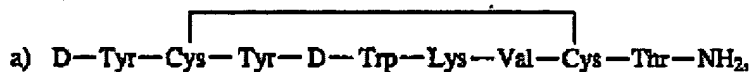
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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 18-19, 23, 24, 25, 36, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coy et al., 5,597,894 (already of record) in view of Bass et al., Molecular Pharmacology.

Coy et al. teach the following somatostatin analogs:

DB-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr(NH₂) and



Coy et al. disclose that the somatostatin analogs can be used in imaging techniques such as using the analogs to identify somatostatin-receptor expressing tumors. See col. 17, lines 12-23; col. 8, lines 25-41; col. 3, lines 25-26; Table 2, WOC-2A.

Coy et al. do not disclose modification of the Cys at position 2 into a D-amino acid. However, the examiner refers to Bass et al., which studies the identification and characterization of somatostatin antagonists, wherein said antagonists contain a core structure of DL-cystein pair at positions 2 and 7. Please see the abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analogs of Coy et al. to have a D-Cys at position 2 because Bass et al.

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teach that somatostatin analogs with a D-Cys(2) and L-Cys(7) display potent antagonist properties. Please see page 713, second column, third full paragraph.

5. Claims 22, 24-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 18-21, 23, 32-43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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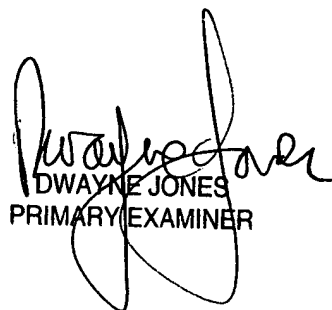
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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Oct. 17, 2005


DWAYNE JONES
PRIMARY EXAMINER